# For immediate release

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<Hospital Heart Program NAME> Now Provides a Treatment for Patients Suffering from Advanced Atrial Fibrillation

*The new EPi-Sense ST™ Coagulation Device is the latest innovation available to treat the 3.5 million patients suffering from advanced atrial fibrillation (AF) in the United States.1*

**We at <HOSPITAL NAME> are pleased to announce that we now offer this therapy to treat patients with advanced atrial fibrillation, who until now had very few treatment options.**

One in 4 adults over age 40 will develop atrial fibrillation in their lifetime.2 AF affects about 37 million people worldwide,3 and about 8 million people in the U.S.4 It also increases a person's risk of stroke, heart failure, dementia, and is linked with increased risk of mortality.

Approximately 45% of patients with atrial fibrillation have Advanced AF, affecting more than 3.5 million patients in the United States.1 “Given that these patients have no comparable treatment options today, our electrophysiology practice will now offer Hybrid AF™ Therapy,” said <HOSPITAL MD, TITLE>.

The minimally invasive Hybrid procedure involves epicardial ablation (outside of the heart) plus endocardial ablation (inside of the heart) thereby treating 2 key trigger areas where AF can begin.

**Clinical Results from more than 1,100 patients with advanced AF who were treated with Hybrid AF Therapy:**

* Up to 88% of patients treated were free from AF5-19
* Up to 94% of patients had reduced AF burden,10,17,18
* Patients reported > 2x improvement in quality of life19-20
* Patients reported > 3x improvement in AF symptoms20

**Treating AF** **is very important because it is a progressive disease.**

Because AF is a progressive condition, patients should receive optimal treatment before their arrhythmia worsens. If AF is not properly treated, it leads to a higher risk of chronic fatigue, decreased activity level, diminished quality of life, and sudden death. Moreover, AF imparts a 3x higher risk of dementia,21 5x risk of stroke,22 and risk of heart failure.23

**Patients who could benefit from the Hybrid AF Therapy** **include patients living with:**

Long-Standing Persistent AF, Permanent AF, Chronic AF, Heart Failure, Scarred Left Atrial Posterior Wall, Enlarged Left Atrium, Failed Endo Catheter Ablation, or failed medical management.

**Symptoms of Advanced AF include:**

* Shortness of breath
* Lightheadedness
* Fainting
* Weakness
* Lack of energy
* Chest pain or Angina

***EPi-Sense® Coagulation System/EPi-Sense ST™ Coagulation Device***

*The EPi-Sense Coagulation System/EPi-Sense ST™ Coagulation Device is intended for the treatment of symptomatic long-standing persistent atrial fibrillation (continuous atrial fibrillation greater than 12 months duration) when augmented in a hybrid procedure with an endocardial catheter listed in the instructions for use, in patients (1) who are refractory or intolerant to at least one Class I and/or III antiarrhythmic drug (AAD); and (2) in whom the expected benefit from rhythm control outweighs the potential known risks associated with a hybrid procedure such as delayed post-procedure inflammatory pericardial effusions.* ***Contraindications*** *include patients with Barrett’s Esophagitis, left atrial thrombus, a systemic infection, active endocarditis, or a localized infection at the surgical site at the time of surgery.* ***Adverse Events:*** *Reported adverse events associated with epicardial ablation procedure may include, but are not limited to, the following: pericardial effusion/cardiac tamponade, pericarditis, excessive bleeding, phrenic nerve injury, stroke/TIA/neurologic complication. Please review the Instructions for Use for a complete listing of contraindications, warnings, precautions and potential adverse events located at the following AtriCure web address:* [*https://www.AtriCure.com/EPi-Sense-Coagulation-Device*](https://www.AtriCure.com/EPi-Sense-Coagulation-Device)*.* ***Warnings:*** *Physicians should consider post-operative anti-inflammatory medication to decrease the potential for post-operative pericarditis. and/or delayed post-procedure inflammatory pericardial effusions. Physicians should consider post-procedural imaging (i.e. 1-3 weeks post-procedure) for detection of post-procedure inflammatory pericardial effusions.* ***Precautions:*** *Precautionary measures should be taken prior to considering treatment of patients: (1) Deemed to be high risk and who may not tolerate a potential delayed post-procedure inflammatory pericardial effusion. (2) Who may not be compliant with needed follow-ups to identify potential safety risks. To ensure patients undergoing treatment with the EPi-Sense device are well informed, the benefits, potential risks and procedural outcomes associated with the EPi-Sense Hybrid Convergent procedure should be discussed with the patient. Physicians should document accordingly in the medical record. Qualified operators are physicians authorized by their institution to perform surgical sub-xyphoid pericardial access. The coagulation devices should be used by physicians trained in the techniques of minimally invasive endoscopic surgical procedures and in the specific approach to be used. Operators should undergo training on the use of EPi-Sense device before performing the procedure. Safety and effectiveness of concomitant left atrial appendage closure was not evaluated in the CONVERGE study. Follow-up should be conducted at approximately 30 days postprocedure to monitor for signs of delayed onset pericarditis or pericardial effusion.*

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